510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K050589

B. Purpose for Submission:

Sysmex is adding the RET-He parameter to the XE-2100 Automated Hematology Analyzer (K992875).

C. Measurand:

The reticulocyte hemoglobin equivalent (RET-He) parameter determines the hemoglobin of reticulocytes.

D. Type of Test:

The RET-He parameter is derived using the reticulocyte forward scattered light signals from the reticulocyte measurement channel and a proprietary Sysmex calculation equation.

E. Applicant:

Sysmex America, Inc.

F. Proprietary and Established Names:

RET-He parameter on the Sysmex XE_2100, Automated Hematology Analyzer

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220, Automated differential cell counter

2. Classification:

   Class II

3. Product code:

   GKZ

4. Panel: Hematology (81)

H. Intended Use:

1. Intended use(s):

   The RET-He parameter on the Sysmex XE-2100, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for in vitro diagnostic use in clinical laboratories.

2. Indication(s) for use:

   N/A

3. Special conditions for use statement(s):

   N/A

4. Special instrument requirements:

   Sysmex XE-Pro and RET Master software are required

I. Device Description:

The XE-2100 is an automated hematology analyzer that uses automated fluorescent flow cytometry which in the reticulocyte channel, using a polymethine dye, also measures the mean value of the forward light scatter histogram of mature red blood cells and reticulocytes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Advia 120 Hematology system CHr parameter

2. Predicate 510(k) number(s):

   K971998

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The RET-He parameter on the XE-2100 determines the hemoglobin of reticulocytes.	The CHr parameter on the Advia 120 determines the hemoglobin of reticulocytes.
Anticoagulant	EDTA	Same
Specimen Type	Peripheral Blood	Same

Differences		
Item	Device	Predicate
Methodology	The reticulocyte parameters are derived using the reticulocyte measurement channel and a proprietary Sysmex calculation equation.	The reticulocyte parameters are derived through a combination of laser light scatter and absorption of a nucleic acid dye.

K. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA, 12-4-2001.

L. Test Principle:

The XE-2100 is an automated hematology analyzer that uses automated fluorescent flow cytometry which in the reticulocyte channel, using a polymethine dye, also measures the mean value of the forward light scatter histogram of mature red blood cells and reticulocytes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Data was assessed according to EP5 recommendation. Total imprecision

ranged between 1.2 and 4.26% CV% on the RET-He parameter and meets manufacturer specifications of ≤5%.

b. Linearity/assay reportable range:

The data showed linearity for RBC (r=1.0) across the tested range of 0.29-7.48 ($x10^6/\mu L$) and for Reticulocyte (r=0.9988) across the tested range of 0.0135 – 0.6770.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability: Samples should be stored from 18 to 26° C (room temperature) or 4-8° C (refrigerated). The variation of RET-He [pg] from 0 hour after blood collection to 24 hours should be within +/-8% (RET#≥$0.010x10^6/\mu L$).

d. Detection limit:

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison data was collected on RET-He parameter on the XE-2100 and compared to the CHr parameter on the Bayer Advia 120. The study included 319 samples that included samples with high WBC counts, lipemia, high bilirubin, platelet clumps, NRBC, atypical lymphocytes, immature granulocytes, blast forms, left shift, atypical/abnormal lymphocytes, iron deficiency, thalassemia, etc. Overall, the XE RET-He parameter showed excellent correlation with the CHr parameter. The correlation (r=0.98) concurred with other evaluation studies ranging from r-values of 0.94-0.96. These conclusions point to the fact that the RET-He parameter on the XE-2100 showed excellent correlation the CHr parameter, the predicate method.

b. Matrix comparison:

N/A

3. Clinical studies:

   a. Clinical Sensitivity:

   N/A

   b. Clinical specificity:

   N/A

   c. Other clinical supportive data (when a. and b. are not applicable):

   Carry over results showed zero percent carryover.

4. Clinical cut-off:

   N/A

5. Expected values/Reference range:

Normal Reference Intervals for RET-He Parameter

RET-He (pg)	Children's Hospital*	Thomas	Johns Hopkins
Mean	32	32.0	33.7
Std. Dev.	1.5	1.9	1.4
N	33	122	31
Range	29-35	28.2-35.7	30.8-36.6

* The age range was 1 to 30 years with a mean age of 16.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Other Supportive Device and Instrument Information:

N/A